DETAILED ACTION

Response to Election of Species requirement

Applicant's election without traverse of Species 3 (i.e., Fig. 3), corresponding to claims 30, 33, 35-37, 47-49, 54 and 58 in the reply filed on 09/02/11 is acknowledged. In view of the fact that claims 31, 32 and 34 were examined in the previous office action, these claims will also be subject to prosecution on the merits in this action, and claims 38-46, 50-53, 55-57 and 59-64 are withdrawn from consideration.

Response to Amendment

The amendment filed on 02/04/11 and 09/02/11 has been entered in the case. Claims 1-37, 47-49, 58 are pending for examination; claims 38-46; 50-53, 55-57, 59-64 are withdrawn from consideration and claims 1-29 have been cancelled.

Claim Objections

Claims 33-34 are objected to because of the following informalities:

(e) and effecting a modification in ~~the~~ **a** tissues adjacent to Schlemm's Canal to increase aqueous outflow.

34. (original) The method of treating Schlemm's Canal of the eye of claim 33 wherein step (e) comprises removal of tissues from ~~the~~ **an** inner wall of Schlemm's Canal.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-37, 47-49, 54 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no

support for what is recited in step (d) of claim 33, i.e., the limitation directed to inserting a microcannula … into the expanded segment of Schlemm's Canal. As indicted on lines 22-23 of page 16 of the instant specification, the microcannula may be positioned to another area of Schlemm's Canal (but not the same expanded segment/area) to repeat the process as needed to increase aqueous outflow to an appropriate level.

For examining purposes, Examiner will interpret this to mean either (a) inserting a microcannula based microsurgical device with an outer diameter … in the expanded segment of Schlemm's Canal; or (b) inserting a microcannula based microsurgical device … into other area of Schlemm's Canal.

Claims 34-37, 47-49, 54 and 58 are rejected due to their dependency on claim 33.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-37, 47-49, 54 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 33, it cannot be determined if the limitation "microcannula with an outer diameter of no more than 350 microns" as recited in step (a) is the same microcannula with a "microcannula based microsurgical device with an outer diameter of no more than 500 microns" as recited in step (d). It appears that applicant means here that the "microcannula" set forth in step (a) is different from the "microcannula" set forth in step (d). If this is the case, claim 33 should be amended so as to read as follows: -- (a) inserting a first microcannula with an outer diameter of no more than 350 microns into Schlemm's Canal; .... (d) inserting a second microcannula based microsurgical device with an outer diameter of no more than 500 microns...--. Alternatively, claim 33 can be interpreted to mean that the microcannula in step (a) is the same as the microcannula in step (d). Therefore, the limitation in step d) "inserting a microcannula based microsurgical device with the outer diameter of no more than 350 microns …" should be changed to --inserting the microcannula based microsurgical device…--.

Claims 34-37, 47-49, 54 and 58 are rejected due to their dependency on claim 33.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stegmann (US 5,486,165) in view of either Rainin (US 5,599,330) or John (US 2004/0122352).

Regarding claim 30, Stegmann discloses a method of treating Schlemm's canal of an eye comprising inserting a flexible microcannula 20, 20', 26 or 35 with an outer diameter equal to 0.15mm (less than 500 micron = 101.6 mm) into Schlemm's canal. Stegmann further discloses that the aqueous humor which is depicted diagrammatically with the arrows 1, 1' and 2, 2' circulating in the region of the anterior chamber v is supplied in the direction of the arrow 3 to Schlemm's canal 15 and removed from therefrom via the upstream tissue 15' (Fig. 4) and via the canalicular venous network, see col. 3, lines 23-29 of Stegmann. Therefore, the step of applying suction is performing for this treatment. Beside that, it is well-known in the art to apply the step of suctioning to remove debris or unwanted material in a patient's eyes during surgery treatment. Stegmann does not disclose the suction level of at least 4 inches of Hg.

Rainin discloses a device and method of aspiration/suction; wherein the suction level of about 30 inches of Hg or less (see col. 4, lines 52-57). Alternatively, John discloses a method and device of aspiration; wherein a pump has a suction level of from 30-45 inches of Hg, see para [0027].

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to use a suction level of at least 4 inches of Hg in Stegmann, in order to remove unwanted fluid or debris from the patient's eye, as taught by both Rainin and John.

Regarding claim 31, Stegmann discloses in Figs. 2-4 that the microcannula comprises openings 24 directed toward an inner radius (see radius R in Fig. 8) thereof to treat specific tissues adjacent to Schlemm's Canal.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stegmann (US 5,486,165) in view of Rainin (US 5,599,330) or John (US 2004/0122352) and further in view of Bylsma (US 6,221,078).

Stegmann in view of Rainin/John does not disclose the limitation of claim 32 that the microcannula comprises an inner member that acts to remove tissue.

Bylsma discloses a device for treating glaucoma comprising an outer member 16 and an inner member 18, 46 or 50 that acts to remove tissue, see col. 5, lines 54-64.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Stegmann in view of Rainin/John so as to include an inner member, as taught by Bylsma, in order to safely remove eye tissue.

Claims 30, 36-37, 47-49 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stegmann (US 5,486,165) in view of Schaaf et al. (US 2001/0053873) and either Rainin (US 5,599,330) or John (US 2004/0122352).

Regarding claims 30, 36 and 37, Stegmann discloses a method of treating Schlemm's Canal of an eye comprising inserting a flexible microcannula 20, 20', 26 or 35 with an outer diameter equal to 0.15mm (i.e., less than 500 micron) into Schlemm's Canal. Stegmann further discloses that the aqueous humor which is depicted diagrammatically with the arrows 1, 1' and 2, 2' circulates in the region of the anterior chamber v which is supplied in the direction of the arrow 3 to Schlemm's canal 15 and removed therefrom via upstream tissue 15' (Fig. 4) and via the canalicular venous network, see col. 3, lines 23-29 of Stegmann. Therefore, the step of applying suction is possible or obvious to perform in this treatment. Beside that, it is well-known in the art to apply the step of suctioning unwanted materials from the eyes surgery treatment. Stegmann does not disclose a suction level of at least 4 inches of Hg, that the suction is applied through a lumen in the flexible microcannula, and that the suction is applied through a lumen in an inner member inserted through the flexible microcannula.

Schaaf discloses a method and device for treating a patient's eyes, the device comprising: a microcannula 30/30.5 inserting into the eye's area; a step of suction is applied through a lumen 39.2 in an inner member 33.2 inserted through the microcannula 30.5, see paragraph [0053] and Fig. 3G.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the method/device of Stegmann so as to include a step of applying suction through a lumen, as taught by Schaff, for the benefit of removing unwanted fluid or tissue particles from the eye.

Rainin discloses a device and method of aspiration/suction, wherein the suction level is about 30 inches of Hg or less (see col. 4, lines 52-57). Alternatively, John discloses a method and device for aspiration wherein a pump suction is applied at a level of from 30-45 inches of Hg, see paragraph [0027].

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the method of Stegmann as modified by Schaaf with a suction level of at least 4 inches of Hg, as taught by Rainin or John, for the benefit of preventing damage to the patient's eye when suctioning unwanted fluid or debris therefrom.

Regarding claim 47, note that Schaaf discloses inserting an inner member 40 through the microcannula having a signaling beacon (i.e., including optical elements 45 and 46).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the method/device of Stegmann so as to include the step of inserting an inner member through the microcannula having a signaling beacon, as taught by Schaff, for the benefit of identifying the location of the microcannula tip in the tissue of the eye.

Regarding claim 48, Schaaf discloses that the cannula has a plurality of lumens and the suction is applied through at least one of the lumens (i.e., lumen 39, see Fig. 3G) in the flexible cannula.

Regarding claim 49, since the lumen 39 is a suction/aspiration lumen, the lumen 39 must be connected to at least one opening (i.e., distal opening of working line/channel 33.2) in the microcannula for aspirating unwanted particles coupled to the aspiration unit 22 via line 22, see paragraph [0053] and Fig. 1. Furthermore, Schaaf also discloses in Figs. 4G-H that tissue particles can be suctioned off through the hollow cylindrical head piece 80/01 having an opening at a distal end thereof.

Regarding claim 54, noted that the Schlemm's Canal having round-shaped about 180 degrees, and also that Stegmann shows inserting the flexible microcannula through Schlemm's Canal. It would have been obvious at the time the invention was made to a person having ordinary skill in the art to insert the microcannula of Stegmann around Schlemm's Canal (i.e., about least 180 degrees thereof) for the purpose of injecting a high viscous medium and thereby expanding Schlemm's Canal.

Claims 33-35 are rejected 35 U.S.C. 103(a) as being unpatentable over Grieshaber et al. (US 6,375,642) in view Stegmann (US 5,486,165).

Previously, a "flexible microcannula" in step (a) and a "microcannula" in step (d) in claim 33 are interpreted as two different microcannulas, see original claims filed 10/17/05. A currently amended of claim 33 requires in step (a) and step (d) are one microcannula. Therefore, the currently amended of claim 33 raises new issues that would require more search. Claims 33-35 can be rejected under new ground rejection and made a Final Rejection.

Examiner will assume that the microcannula in step a) is same as the microcannula in step d). Therefore, the limitation in step d) "inserting a microcannula based microsurgical device with an outer diameter of no more than 500 microns ..." should be changed as --- inserting the microcannula based microsurgical device... ---. See rejection 112, 2nd paragraph above. Examiner will also assume that inserting a microcannula based microsurgical device with an outer diameter of no more than 350 microns into other area of Schlemm's Canal. See rejection 112, 1st paragraph above.

Regarding claim 33, Grieshaber discloses a method for treating Schlemm's Canal of an eye comprising the steps of:

a) inserting a microcannula 24 into the Schlemm's Canal;

b) injecting a flowable material (i.e., sodium hyaluronate solution, see col. 5, lines 4-13) to expand at least a segment of Schlemm's Canal to facilitate microcannula access, see col. 3, lines 5-62, and Fig. 4;

c) removing the microcannula 24, see col. 5, lines 14-16;

d) inserting the microcannula based microsurgical device into the Schlemm's Canal, see col. 4, lines 42-49; and

e) effecting a modification in the tissue adjacent to the Schlemm's Canal to increase aqueous outflow, see abstract and Summary of the Invention.

Grieshaber does not disclose that an outer diameter of the microcannula is no more than 350 microns.

Stegmann discloses a similar method for treating Schlemm's Canal of an eye comprising a microcannula with an outer diameter of 0.15 mm which is less than 350 micron.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the method/device of Grieshaber with an outer diameter of microcannula less than 350 micron, as taught by Stegmann, for the benefit of preventing damage to the tissue of a patient's eye.

Regarding claim 34, Grieshaber includes the step of removing of tissues (i.e., cutting scleral flap 10 and schleral flap 12) from the inner wall of Schlemm's Canal, see Figs. 1, 3 and 5. Stegmann also including a step of removal of tissues 13' from an inner wall of Schlemm's Canal, see Fig. 4. According to www.dictionary.com, the term "remove" or "removing" defines as to move from a place or position. In this case, Grieshaber discloses cutting and moving scleral flap 10 and schleral flap 12 away from the inner wall of Schlemm's Canal.

Regarding claim 35, Grieshaber including a step of placing of an implant 18 at least partially residing in Schlemm's Canal, see Figs. 13-14.

Claim 58 is rejected 35 U.S.C. 103(a) as being unpatentable over Grieshaber et al. (US 6,375,642) in view Stegmann (US 5,486,165) in view of John (US 2004/0122352).

Grieshaber in view Stegmann discloses the invention substantially as claimed invention except for the limitation that a level suction is at least 4 inches of Hg through the microcannula.

John discloses a tubular insertion into the eye of a patient and applying a level of suctioning which ranges from 30-45 inches of Hg.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the method and device of Grieshaber in view of Stegmann with a suction level from 30-45 inches of Hg, as taught by John, in order to remove liquid from the eye's tissue without damaging eye tissue.

Response to Arguments

Applicant's arguments filed 02/04/11 have been fully considered but they are not persuasive.

1) Applicant argues on pg 8 of Remarks 02/04/11 that:

> 1. Claims 33 and 34 were rejected under 35 USC 102(b) as anticipated by Stegmann (US 5486165).
> 2. Claim 33 has been amended to clarify that the microcannula based microsurgical device is inserted into the segment of Schlemm's Canal that has been previously expanded using the flexible microcannula. By contrast, in the Stegmann reference, the second tube 20' is configured as a mirror image of the first tube 20 so that it can be inserted into a different segment of Schlemm's Canal. (Column 4, lines 42-49.) The configuration of the second tube 20' makes it unsuitable for insertion into the same segment of Schlemm's Canal that was previously occupied by the first tube 20. (See FIG. 8.)
>
> Claim 34 further distinguishes Stegmann by the novel step of "removal of tissues from the inner wall of Schlemm's Canal." Stegmann does not disclose the removal of tissues from within Schlemm's Canal. The only direct manipulation of tissue that occurs in Stegmann is the initial incision that is made in order to gain access to Schlemm's Canal. (See FIGS. 3 and 4.) A flap 13' is made, but no tissue is removed. Furthermore, the incision is made from the scleral surface, therefore the flap 13' is made on the ***outer wall*** of Schlemm's Canal, rather than the ***inner wall***.

This argument is not persuasive because as mentioned the above that the instant claim 33 were amended and raises new issues that would require more search. For example, in the original claim 33 filed 10/17/05, the "flexible microcannula" set forth in step (a) and the "microcannula" set forth in step (d) of claim 33 are interpreted as two different microcannulas. Currently amended claim 33 requires in step (a) and step (d) the possibility that only one microcannula is being claimed, see rejection 112, 1st and 2nd

paragraph above. Therefore, claims 33-35 are now rejected using a new ground rejection, see the rejection above.

2) Applicant further argues on pg 8 of Remarks 02/04/11 that:

> 3. Examiner stated that claim 35 was rejected under **35 USC 102(b)** as anticipated by Stegmann (US 5486165) in view of Grieshaber (US 2002/0013546).
>
> 4. This is an improper rejection under 35 USC 102(b) because references cannot be combined under this statute. Examiner is requested to withdraw the rejection or to clarify the rejection in a subsequent ***non-final*** Office Action.

A typographic error of claim 35 was made in previous Office Action dated 08/04/10. As seen that claim 35 is located under 103 Rejection section and more than one reference (as noted above, claim 33 was amended, thus raising new issues). Claim 33 is now introduced new ground rejection, since claim 35 is depends from claim 33 and also is being rejected under a new ground rejection, see the rejection above for more details.

3) Applicant argues on pg 9 of Remarks 02/04/11 that:

> 6. Applicant respectfully traverses the rejection of claims 30-31. Examiner erroneously states that Stegmann utilizes suction in the disclosed method; however there is no mention of suction anywhere in the reference. The section cited by Examiner (column 3, lines 23-29) has nothing to do with the application of suction. Stegmann is actually describing the natural flow of aqueous humour within the eye, as shown in FIG. 2. Applicant notes that there are not even any devices present within the eye shown in FIG. 2 that could apply the fictitious suction alleged by Examiner. Applicant contends that Examiner would never have made this misinterpretation of the reference without the hindsight provided by applicant's own patent application.
>
> There is no suggestion or motivation in the Stegmann reference to apply suction through any part of the disclosed apparatus. Furthermore, applicant points out that Rainin and John both disclose devices that apply suction to the ***exterior*** of a patient's eye. There is no suggestion or motivation in these secondary references to apply suction through a device that is inserted into Schlemm's Canal within the eye.

This argument is not persuasive because Stegmann clearly states that the aqueous humour circulating in the region of the anterior chamber v is supplied in the direction of the arrow 3 to Schlemm's canal 15 and is **removed** from the latter, see col. 3, lines 23-27. Although Stegmann does not clearly indicate the method or how to remove the aqueous humor liquid, the method of suctioning unwanted material (i.e. liquid or debris) is very well-known in the eye surgery art. Moreover, Rainin and John both disclose removing unwanted materials from the eyes by suctioning with a level of about 30-45 inches of Hg or less. Given such a teaching by Rainin and John, a person having ordinary skill in the art would have easily recognized the benefit of modifying the method of Stegmann so as to use suctioning at a level less than 30-45 inches of Hg, as taught by either Rainin or John, i.e., aspirating unwanted materials without damaging the eye tissue.

4) Applicant further argues on pg 9 of the Remarks 02/04/11 that:

> There is no suggestion or motivation in the Stegmann reference to apply suction through any part of the disclosed apparatus. Furthermore, applicant points out that Rainin and John both disclose devices that apply suction to the ***exterior*** of a patient's eye. There is no suggestion or motivation in these secondary references to apply suction through a device that is inserted into Schlemm's Canal within the eye.
> Examiner's rejection was based on an erroneous interpretation of the primary reference. Without this misinterpretation, there is no suggestion or motivation to combine the references as proposed by Examiner. Examiner is respectfully requested to withdraw the rejection of claims 30-31.

This argument is not persuasive because claim 30 only requires applying suction at a level of at least 4 inches of Hg. Claim 30 does not require applying suction to the exterior of a patient's eye. Moreover, John discloses an aspiration device for an eye which includes a tubular member (i.e., a flexible microcannula) for inserting into the patient's eye for suctioning unwanted materials.

5) Applicant further argues on pgs 9-10 of the Remarks 02/04/11 that:

> 7. Claim 32 was rejected under 35 USC 103(a) as unpatentable over Stegmann (US 5486165) in view of Rainin (US 5599330) or John (US 2004/0122352) and further in view of Bylsma (US 2006/0221078).
> 8. As with claims 30-31 above, Examiner's rejection was based on an erroneous interpretation of Stegmann, the primary reference. Without this misinterpretation, there is no suggestion or motivation to combine Rainin or John with Stegmann, as proposed by Examiner. For this reason, Examiner is respectfully requested to withdraw the rejection of claim 32.
>
> Furthermore, as pointed out in reference to claim 34 above, Stegmann does not disclose the removal of material from within Schlemm's canal as erroneously stated by Examiner. There is no suggestion or motivation to combine from Bylsma because it is directed to an entirely different approach to treating glaucoma. Rather than repairing Schlemm's canal to establish normal drainage, Bylsma seeks to bypass the normal drainage pathway by installing a glaucoma drain 100 to drain aqueous humour externally. Without Examiner's misinterpretation of the primary reference, there is no suggestion or motivation to combine the tissue cutting device of Bylsma with Stegmann. For this additional reason, Examiner is also requested to withdraw the rejection of claim 32.

This argument is not persuasive because, as noted the above, claims 30 and 31 are rejected under 35 U.S.C 103 (a) as being unpatentable over Stegmann in view of Rainin or John still deemed proper. As to the limitation in claim 32 that the microcannula comprises an inner member that acts to remove tissue, note that Stegmann also shows in Fig. 4 the step of removing/cutting tissue. Note that the term "removing" is defined in www.dictionary.com to mean moving from a place or position, taking away or taking off. In this case, Stegmann shows that tissue 13' is moved away from tissue 13, see Fig. 4. Therefore, Stegmann includes the step of removing the tissue, but does not disclose the step of using the inner member of microcannula to remove tissue. Meanwhile, Bylsma clearly discloses a surgical apparatus for the eye including a microcannula 16, an inner member 18, 46 or 50 that acts to remove tissue, see col. 5, lines 54-64. Therefore, one skilled in the art would have easily recognized the benefit

of modifying the device/method of Stegmann so as to include an inner member that acts to remove tissue, as suggested by Bylsma, in order to create small wound in the eye so that the physician can remove tissue or unwanted debris in different location within Schlemm's Canal rather than tissue 13.

As to claim 34, this claim requires the step of removing tissue from the inner wall of the Schlemm's Canal but does not require using an inner member of microcannula to remove tissue as required in claim 32. In this case, as mentioned in the rejection of claim 34 above, Grieshaber clearly disclose removing tissue (i.e., cutting scleral flap 10 and schleral flap 12) from the inner wall of Schlemm's Canal, see Figs. 1, 3 and 5. Alternatively, Stegmann also discloses removal of tissue 13' from an inner wall of Schlemm's Canal, see Fig. 4.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/QUYNH-NHU H VU/
Examiner of Art Unit 3763